

* **SECTION 1: Identification of the substance/mixture and of the company/undertaking**

1.1 Product identifier

Trade name: Biocrates® Bile Acids Kit Column (for HPLC and UHPLC Systems)

UFI: CT90-20PQ-Q007-8MD5

1.2 Relevant identified uses of the substance or mixture and uses advised against

Application of the substance / the mixture

Analytical Chemistry
Chromatography column

1.3 Details of the supplier of the safety data sheet

Manufacturer/Supplier:

biocrates life sciences ag

Eduard-Bodem-Gasse 8

A-6020 Innsbruck

T: +43 512 57 98 23

F: +43 512 57 98 23 329

Further information obtainable from: Email: office@biocrates.com

1.4 Emergency telephone number:

+43 512 57 98 23

Available during office hours:

Mo-Fr: 9 a.m. - 5 p.m.

Call the national emergency number!

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008

Flam. Liq. 2 H225 Highly flammable liquid and vapour.

Eye Irrit. 2 H319 Causes serious eye irritation.

Additional information: For the wording of the hazard categories, see section 16.

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008

The product is classified and labelled according to the CLP regulation.

Hazard pictograms



GHS02



GHS07

Signal word Danger

Hazard statements

H225 Highly flammable liquid and vapour.

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Trade name: Biocrates® Bile Acids Kit Column (for HPLC and UHPLC Systems)

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H319 Causes serious eye irritation.

Precautionary statements

P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

P280 Wear protective gloves / eye protection.

P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

2.3 Other hazards

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

Determination of endocrine-disrupting properties

The product does not contain substances with endocrine-disrupting properties ≥ 0.1 %(w/w).

* **SECTION 3: Composition/information on ingredients**

3.2 Mixtures

Description:

Mixture (encapsulated in article)

Contains: Organosilane bonded silica gel.

Note: To the best of our knowledge, the acute and chronic toxicological properties of bonded silica gels have not been investigated. This product contains synthetic amorphous silica, and should not be confused with crystalline silica such as quartz, cristobalite, or tridymite, or with diatomaceous earth or other naturally occurring forms of amorphous silica that frequently contain crystalline forms of silica.

Mixture of substances listed below with nonhazardous additions.

Dangerous components:

CAS: 75-05-8	acetonitrile	15 - < 30%
EINECS: 200-835-2	 Flam. Liq. 2, H225	
Index number: 608-001-00-3	 Acute Tox. 4, H302; Acute Tox. 4, H312; Acute Tox. 4, H332; Eye Irrit. 2, H319	
RTECS: AL 7700000		

Additional information: For the wording of the listed hazard phrases refer to section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

General information:

In case of discomfort or doubt, seek medical advice.

If unconscious, use a stable lateral position and do not administer anything through mouth.

Immediately remove any clothing soiled by the product.

After inhalation:

Supply fresh air or oxygen; call for doctor.

In case of unconsciousness place patient stably in side position for transportation.

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After skin contact:

Immediately rinse with water.

Take off immediately all contaminated clothing and wash it before reuse.

Seek medical treatment in case of complaints.

After eye contact:

Rinse opened eye for several minutes under running water.

Remove contact lenses, if present and easy to do. Continue rinsing.

Seek medical treatment.

After swallowing:

Rinse mouth thoroughly with cold water. Do not induce vomiting. If the patient is fully conscious, give one or two glass of water to drink. Get medical attention immediately.

4.2 Most important symptoms and effects, both acute and delayed

No further relevant information available.

4.3 Indication of any immediate medical attention and special treatment needed

Depending on the condition of the patients, the doctor must assess the symptoms and the overall general condition.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing agents:

CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

For safety reasons unsuitable extinguishing agents: Water with full jet

5.2 Special hazards arising from the substance or mixture

Highly flammable liquid and vapour.

Runoff to sewer may create fire or explosion hazard.

In a fire or if heated, a pressure increase will occur and the container may burst, with the risk of a subsequent explosion.

In case of fire, the following can be released:

CO_x, NO_x

cyanides

Metal Oxides/Oxides

5.3 Advice for firefighters

Protective equipment:

Wear self-contained respiratory protective device.

Wear fully protective suit.

Additional information

Remove container from fire, if possible without risk.

Cool endangered receptacles with water spray.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Restricted access to the affected area until cleaning work is completed.

Wear protective equipment. Keep unprotected persons away.

Ensure adequate ventilation

Avoid contact with skin and eyes.

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Do not breathe vapour/spray.

Remove ignition sources, if possible without danger.

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

Take action to prevent static discharges.

6.2 Environmental precautions:

Do not allow to enter sewers/ surface or ground water.

Inform respective authorities in case of seepage into water course or sewage system.

6.3 Methods and material for containment and cleaning up:

Absorb with liquid-binding, inert material (sand, diatomite, acid binders, universal binders).

Dispose contaminated material as waste according to section 13.

Ensure adequate ventilation.

Use non-sparking tools.

6.4 Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

SECTION 7: Handling and storage**7.1 Precautions for safe handling**

Ensure good ventilation/exhaustion at the workplace.

Keep receptacles tightly sealed.

Avoid contact with skin and eyes.

Avoid breathing mist/vapours/spray.

Use personal protective equipment as required.

Observe protective measures and safety instructions.

Information about fire - and explosion protection:

Keep ignition sources away - Do not smoke.

Protect against electrostatic charges.

Use explosion-proof apparatus / fittings and spark-proof tools.

7.2 Conditions for safe storage, including any incompatibilities**Storage:****Requirements to be met by storerooms and receptacles:**

Store in a cool location.

Store receptacle in a well ventilated area.

Protect from heat and direct sunlight.

Store in accordance with local/regional/national/international regulations.

Information about storage in one common storage facility: Store away from incompatible materials.

Further information about storage conditions:

Store only in the original receptacle.

Keep container tightly sealed.

Store in cool, dry conditions in well sealed receptacles.

Storage class: 3**7.3 Specific end use(s)** No further relevant information available.

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* **SECTION 8: Exposure controls/personal protection**

8.1 Control parameters

Ingredients with limit values that require monitoring at the workplace:

CAS: 75-05-8 acetonitrile

IOELV (EU)	Long-term value: 70 mg/m ³ , 40 ppm Skin
MAK (Austria)	Short-term value: 280 mg/m ³ , 160 ppm Long-term value: 70 mg/m ³ , 40 ppm
AGW (Germany)	Long-term value: 17 mg/m ³ , 10 ppm 2(II);DFG, EU, H, Y
LEP (Spain)	Long-term value: 68 mg/m ³ , 40 ppm vía dérmica, VLI
VLEP (France)	Long-term value: 70 mg/m ³ , 40 ppm Risque de pénétration percutanée
WEL (Great Britain)	Short-term value: 102 mg/m ³ , 60 ppm Long-term value: 68 mg/m ³ , 40 ppm
TWA (Italy)	Long-term value: 34 mg/m ³ , 20 ppm Cute, A4
VL (Italy)	Long-term value: 35 mg/m ³ , 20 ppm Cute
WGW (Netherland)	Long-term value: 34 mg/m ³ , 20 ppm

Regulatory information

IOELV (EU): (EU) 2019/1831

MAK (Austria): GKV 2021, 330. Verordnung, 02.12.2024, Teil 2

AGW (Germany): TRGS 900

LEP (Spain): Límites de exposición profesional para agentes químicos

VLEP (France): ED 1487 26.04.2024

WEL (Great Britain): EH40/2020

TWA (Italy): Valori Limite di Soglia

VL (Italy): D.lgs. n. 135/2024, Allegato A

WGW (Netherland): Grenswaarden gezondheidsschadelijke stoffen

DNELs

CAS: 75-05-8 acetonitrile

Oral	Long-term exposure - systemic effects	0.4 mg/kg bw/d (consumer)
	short-term exposure - systemic effects	0.6 mg/kg bw (consumer)
Dermal	Long-term exposure - systemic effects	1.2 mg/kg bw/d (consumer)
		20 mg/kg bw/d (workers)
Inhalative	Long-term exposure - systemic effects	2.4 mg/m ³ (consumer)
		70 mg/m ³ (workers)
	Long-term exposure - local effects	70 mg/m ³ (workers)

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	short-term exposure - systemic effects	22 mg/m ³ (consumer) 102 mg/m ³ (workers)
	short-term exposure - local effects	22 mg/m ³ (consumer) 102 mg/m ³ (workers)

PNECs

CAS: 75-05-8 acetonitrile

fresh water	10 mg/l
sea water	1 mg/l
intermittent release (fresh water)	10 mg/l
STP	32 mg/l
sediment (fresh water)	40.5 mg/kg dw
sediment (sea water)	4.05 mg/kg dw
soil	2.23 mg/kg dw

Additional information: The lists valid during the making were used as basis.

8.2 Exposure controls

Appropriate engineering controls

Technical measures and the use of suitable working methods take priority over the use of personal protective equipment.

No further data; see section 7.

Individual protection measures, such as personal protective equipment

General protective and hygienic measures:

The usual precautionary measures are to be adhered to when handling chemicals.

Keep away from foodstuffs, beverages and feed.

Do not eat or drink while working.

Wash hands before breaks and at the end of work.

Avoid contact with the eyes and skin.

Immediately remove all soiled and contaminated clothing.

Protective clothing needs to be selected specifically for the workplace, depending on concentrations and quantities of the hazardous substances handled. The chemical resistance of the protective equipment should be enquired at the respective supplier.

Respiratory protection: Use suitable respiratory protective device in case of insufficient ventilation.

Hand protection



Protective gloves

EN 374

Material of gloves

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

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Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation.

Penetration time of glove material

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

Eye/face protection



Tightly sealed goggles

EN 166

Body protection:

antistatic protective clothing

Select type and quality of protection clothes depending on concentration and quantity at the workplace.

Environmental exposure controls

Do not allow to enter sewers/ surface or ground water.

Inform respective authorities in case of seepage into water course or sewage system.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

General Information

Physical state

Solid

Colour:

Not determined.

Odour:

Ether-like

Odour threshold:

No information available.

Melting point/freezing point:

No information available.

Boiling point or initial boiling point and boiling range

No information available.

Flammability

Not applicable.

Lower and upper explosion limit

Lower:

No information available.

Upper:

No information available.

Flash point:

-18 - +23 °C

Decomposition temperature:

No information available.

pH

No information available.

Viscosity:

Kinematic viscosity

No information available.

Dynamic:

No information available.

Solubility

water:

Mobile phase: Soluble

Stationary phase: Insoluble

Partition coefficient n-octanol/water (log value)

75-05-8 acetonitrile -0,34 log Kow

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Vapour pressure: No information available.

Density and/or relative density

Density: No information available.

Vapour density No information available.

9.2 Other information

Appearance:

Form: solid (with flammable liquid)

Important information on protection of health and environment, and on safety.

Ignition temperature:

75-05-8	acetonitrile	524 ° C
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Explosive properties: No information available.

Change in condition

Oxidising properties No information available.

Evaporation rate No information available.

Information with regard to physical hazard classes

Explosives void

Flammable gases void

Aerosols void

Oxidising gases void

Gases under pressure void

Flammable liquids Highly flammable liquid and vapour.

Flammable solids void

Self-reactive substances and mixtures void

Pyrophoric liquids void

Pyrophoric solids void

Self-heating substances and mixtures void

Substances and mixtures, which emit flammable

gases in contact with water void

Oxidising liquids void

Oxidising solids void

Organic peroxides void

Corrosive to metals void

Desensitised explosives void

SECTION 10: Stability and reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical stability No decomposition if used and stored according to specifications.

10.3 Possibility of hazardous reactions

No dangerous reactions are to be expected when used as intended.

10.4 Conditions to avoid

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

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Trade name: Biocrates® Bile Acids Kit Column (for HPLC and UHPLC Systems)

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10.5 Incompatible materials:

oxidizing agent

hydrogen fluoride

10.6 Hazardous decomposition products:

No decomposition if used and stored according to specifications.

*** SECTION 11: Toxicological information****11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008****Acute toxicity** Based on available data, the classification criteria are not met.**LD/LC50 values relevant for classification:****AbsoluteIDQ® p400 HR Kit UHPLC Column**

Oral LD50 > 2000 mg/kg (mouse)

Dermal LD50 4,231 mg/kg

Inhalative LC50/4 h 42.3 mg/l

CAS: 75-05-8 acetonitrile

Oral LD50 617 mg/kg (mouse)

Source: ECHA, European Chemical Agency, <http://echa.europa.eu/>

2,460 mg/kg (rat)

Dermal LD50 mg/kg (Rabbit)

Source: ECHA, European Chemical Agency, <http://echa.europa.eu/>**Primary irritant effect:****Skin corrosion/irritation** Based on available data, the classification criteria are not met.**Serious eye damage/irritation**

Causes serious eye irritation.

Respiratory or skin sensitisation Based on available data, the classification criteria are not met.**Germ cell mutagenicity** Based on available data, the classification criteria are not met.**Carcinogenicity** Based on available data, the classification criteria are not met.**Reproductive toxicity** Based on available data, the classification criteria are not met.**STOT-single exposure** Based on available data, the classification criteria are not met.**STOT-repeated exposure** Based on available data, the classification criteria are not met.**Aspiration hazard** Based on available data, the classification criteria are not met.**11.2 Information on other hazards****Endocrine disrupting properties**

None of the ingredients is listed.

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Trade name: Biocrates® Bile Acids Kit Column (for HPLC and UHPLC Systems)

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SECTION 12: Ecological information

12.1 Toxicity

Aquatic toxicity:

CAS: 75-05-8 acetonitrile

LC50 (96 h)	1,640 mg/l (fish) Source: ECHA, European Chemical Agency, http://echa.europa.eu/
NOEC (21 d)	102 mg/l (fish)
EC50 (72 h)	3,560 mg/l (algae) Source: ECHA, European Chemical Agency, http://echa.europa.eu/
ErC50 (72 h)	9,696 mg/l (algae)

12.2 Persistence and degradability No further relevant information available.

12.3 Bioaccumulative potential No further relevant information available.

12.4 Mobility in soil No further relevant information available.

12.5 Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

12.6 Endocrine disrupting properties

The product does not contain substances with endocrine disrupting properties.

12.7 Other adverse effects

Additional ecological information:

General notes:

Water hazard class 2 (German Regulation) (Self-assessment): hazardous for water

Do not allow product to reach ground water, water course or sewage system.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Recommendation

Must not be disposed together with household garbage. Do not allow product to reach sewage system.

Only dispose of product residues via authorised companies according to local legislation.

European waste catalogue

Notes: The European Waste Catalogue (EWC) classifies waste materials and categorises them according to what they are and how they were produced. This may cause other classifications. The final decision belongs to the last user.

16 03 05*	organic wastes containing hazardous substances
HP3	Flammable
HP4	Irritant - skin irritation and eye damage
HP6	Acute Toxicity

Uncleaned packaging:

Recommendation:

Dispose of packaging according to regulations on the disposal of packagings.

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Trade name: Biocrates® Bile Acids Kit Column (for HPLC and UHPLC Systems)

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Packagings that may not be cleansed are to be disposed of in the same manner as the product.

SECTION 14: Transport information

14.1 UN number or ID number

ADR/RID/ADN, IMDG, IATA

UN3175

14.2 UN proper shipping name

ADR/RID/ADN

3175 SOLIDS CONTAINING FLAMMABLE LIQUID,
N.O.S. (ACETONITRILE)

IMDG, IATA

SOLIDS CONTAINING FLAMMABLE LIQUID, N.O.S.
(ACETONITRILE)

14.3 Transport hazard class(es)

ADR/RID/ADN, IMDG, IATA



Class

4.1 Flammable solids, self-reactive substances,
polymerizing substances and solid desensitized
explosives

Label

4.1

14.4 Packing group

ADR/RID/ADN, IMDG, IATA

II

14.5 Environmental hazards:

Not applicable.

14.6 Special precautions for user

Warning: Flammable solids, self-reactive substances,
polymerizing substances and solid desensitized
explosives

Hazard identification number (Kemler code):

40

EMS Number:

F-A,S-I

Stowage Category

B

Stowage Code

SW2 Clear of living quarters.

**14.7 Maritime transport in bulk according to IMO
instruments**

Not applicable.

Transport/Additional information:

ADR/RID/ADN

Limited quantities (LQ)

1 kg

Excepted quantities (EQ)

Code: E2

Maximum net quantity per inner packaging: 30 ml

Maximum net quantity per outer packaging: 500 ml

Transport category

2

Tunnel restriction code

E

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Trade name: Biocrates® Bile Acids Kit Column (for HPLC and UHPLC Systems)

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IMDG**Limited quantities (LQ)**

1 kg

Excepted quantities (EQ)

Code: E2

Maximum net quantity per inner packaging: 30 ml

Maximum net quantity per outer packaging: 500 ml

UN "Model Regulation":

UN 3175 SOLIDS CONTAINING FLAMMABLE LIQUID, N.O.S. (ACETONITRILE), 4.1, II

SECTION 15: Regulatory information**15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture****Directive 2012/18/EU****Named dangerous substances - ANNEX I** None of the ingredients is listed.**Seveso category** P5c FLAMMABLE LIQUIDS**Qualifying quantity (tonnes) for the application of lower-tier requirements** 5.000 t**Qualifying quantity (tonnes) for the application of upper-tier requirements** 50.000 t**REGULATION (EC) No 1907/2006 ANNEX XVII** Conditions of restriction: 3**DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment – Annex II**

None of the ingredients is listed.

REGULATION (EU) 2019/1148**Annex I - RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3))**

None of the ingredients is listed.

Annex II - REPORTABLE EXPLOSIVES PRECURSORS

None of the ingredients is listed.

Regulation (EC) No 273/2004 on drug precursors

None of the ingredients is listed.

Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors

None of the ingredients is listed.

National regulations:**Information about limitation of use:** Employment restrictions concerning juveniles must be observed.**15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.*** SECTION 16: Other information**

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

This Safety Data Sheet is in compliance with Regulation (EC) No 1907/2006, Article 31 as amended by Regulation (EU) 2020/878.

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Trade name: Biocrates® Bile Acids Kit Column (for HPLC and UHPLC Systems)

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Relevant phrases

H225 Highly flammable liquid and vapour.

H302 Harmful if swallowed.

H312 Harmful in contact with skin.

H319 Causes serious eye irritation.

H332 Harmful if inhaled.

Training hints

Regular training of staff involved in the transport of dangerous goods (in accordance with Chapter 1.3 ADR).

Before handling, storage or use for the first time, employees must be informed about the properties of the substance and about measures taken to ensure safety and environmental protection.

Classification according to Regulation (EC) No 1272/2008

Flammable liquids	On basis of test data
Serious eye damage/irritation	The classification of the mixture is generally based on the calculation method using substance data according to Regulation (EC) No 1272/2008.

Department issuing SDS:

UmEnA GmbH

<http://umena.at>

Email: office@umena.at

Date of previous version: 10.09.2024

Version number of previous version: 1.6

Abbreviations and acronyms:

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

DNEL: Derived No-Effect Level (REACH)

PNEC: Predicted No-Effect Concentration (REACH)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

ATE: Acute toxicity estimate values

Flam. Liq. 2: Flammable liquids – Category 2

Acute Tox. 4: Acute toxicity – Category 4

Eye Irrit. 2: Serious eye damage/eye irritation – Category 2

*** Data compared to the previous version altered.**